IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	C.A. No. 21-1694-RGA Redacted Version of D.I. 258
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	

FERRING'S OPENING BRIEF IN SUPPORT OF ITS MOTIONS FOR SUMMARY JUDGMENT AND *DAUBERT* MOTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

I. INTRODUCTION

Plaintiffs Ferring Pharmaceuticals Inc. and Rebiotix Inc. ("Rebiotix") (collectively, "Ferring") move for summary judgment on eight issues. Ferring also moves to exclude evidence and testimony from Finch/UMN's damages expert, James E. Malackowski.

II. NATURE AND STAGE OF THE PROCEEDINGS

Ferring filed this action against Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., and Finch Therapeutics Holdings, LLC (collectively, "Finch") on December 1, 2021, seeking a declaration that seven patents naming Thomas Borody as the inventor and purportedly assigned to Finch ("Borody patents") are invalid or not infringed by Ferring's REBYOTA drug product. (D.I. 1.) REBYOTA is a microbiome product that is indicated for the prevention of recurrence of *C. difficile* infection ("CDI") after antibiotic treatment. During the litigation, Finch obtained and asserted two additional Borody patents and added the Regents of the University of Minnesota ("UMN"; collectively with Finch, "Finch/UMN") as counterclaimants to assert three patents assigned to UMN ("UMN patents"). Fact and expert discovery is complete and a five day jury trial is scheduled to begin on May 20, 2023. The remaining Borody patents are attached as Exhibits 1, 2, 3, and 4. The remaining UMN patents are attached as Exhibits 5 and 6. The text of the asserted claims is reproduced in Ex. 7.

Currently, the following claims of the Borody patents are at issue:

Patent	Asserted claim(s)
US Patent Number 10, 463,702 ("the '702 patent")	11
US Patent Number 10,675,309 ("the '309 patent")	12 (unasserted), 16, 21
US Patent Number 11,491,193 ("the '193 patent")	1, (unasserted), 4, 8, 14
US Patent Number 11,541,080 ("the '080 patent")	1 (unasserted), 2, 5, 9

Currently, the following claims of the UMN patents are at issue:

Patent	Asserted claim(s)
US Patent Number 10,251,914 ("the '914 patent")	4 (unasserted), 7, 9 (unasserted), 18, 23
US Patent Number 10,286,012 ("the '012 patent")	1 (unasserted), 7, 9, 12

On July 6, 2023, Ferring filed a motion to dismiss the Borody patents for lack of standing. (D.I. 208.) The motion is fully briefed. (D.I. 221, 232.) Both parties have requested oral argument. (D.I. 234, 238.) The Court referred the motion to Magistrate Judge Hall on October 4, 2023. The motion is still pending and no argument has been scheduled. Because standing is a threshold jurisdictional issue, it must be resolved before the Court can consider any issues on the merits, including the issues raised in section III of this brief. *Media Techs. Licensing, LLC .v Upper Deck Co.*, 334 F.3d 1366, 1369 (Fed. Cir. 2003); *Wayne Land & Mineral Grp., LLC v. Del. River Basin Comm'n*, 959 F.3d 569, 574 (3d Cir. 2020).

III. FERRING'S MOTIONS FOR SUMMARY JUDGMENT

Ferring submits this brief in support of eight motions for summary judgment: (i) partial summary judgment of no copying because Finch/UMN cannot meet its burden to show copying, either in support of its allegations of secondary considerations of non-obviousness or its allegations of willful and induced infringement, and absent copying, the Court should also enter summary judgment of no willful infringement; (ii) the asserted claims of the UMN patents are invalid as indefinite because they contain an improper Markush group; (iii) the asserted claims of the UMN patents are invalid under Section 112 because they lack written description support for the % change limitation and the Markush group; (iv) Finch/UMN is barred from asserting that the particle size limitations in the UMN patents are infringed under the doctrine of equivalents and Ferring does not literally infringe those limitations; (v) the asserted claims of the UMN patents are invalid under Section 112 because, as construed, the term "extract" in the UMN patents lacks written description support; (vi) Ferring does not infringe any asserted claims of the

'702, '309, or '193 patents because REBYOTA is not approved for treating CDI; (vii) the asserted claim of the '702 patent is invalid under Section 112 because "substantially entire microbiota" is indefinite; and (viii) all asserted claims of the Borody patents are unpatentable under Section 101. *See generally Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

A. Partial summary judgment of no copying is appropriate, as is summary judgment of no willful infringement

1. Summary of argument

Finch/UMN's allegations of willful and induced infringement and its reliance on secondary considerations of non-obviousness cannot be predicated on copying anything in the asserted claims of the Borody or UMN patents or the allegedly disclosed inventions. With respect to willfulness and induced infringement, the copying evidence and testimony of Finch/UMN's expert, Dr. Benson, improperly focuses on alleged conduct that occurred well before the Borody and UMN patents even issued. And he fails to identify any nexus between the alleged conduct and the allegedly copied inventions, which makes copying irrelevant as a secondary consideration. Given these failures, partial summary judgment of no copying is appropriate. And without copying, Finch/UMN cannot prove willfulness.

2. Statement of facts

Finch/UMN's copying theory, as set forth in the opening and rebuttal expert reports of Dr. Benson, Ex. 9, ¶¶51-58; Ex. 10, ¶¶1276-1283 (Borody patents), ¶¶1374-1388 (UMN patents) fails as a matter of law to make a *prima facie* claim of copying.

In terms of the asserted claims of the UMN patents, all that Dr. Benson's reports show is that Rebiotix's co-founder, Lee Jones, was a "CEO in Residence" at UMN for a time prior to the UMN inventions (in 2011 or earlier, *see* Ex. 9, ¶53), where she had "access" to or "awareness" of UMN's provisional patent application and confidential documents, *id.*, brought confidential

information from UMN to Rebiotix and also reviewed and shared UMN publications, *id.*, ¶54, and credited UMN for providing inspiration, *id.*, ¶55. Additionally, Dr. Benson notes that two other individuals, Mr. Hlavka and Mr. Berman, were also "aware" of UMN's and Dr. Borody's work. *Id.*, ¶¶56-58; s*ee also generally* Ex. 10, ¶¶1374-1388 (same). Dr. Benson's narrative has no nexus to the inventions claimed in the UMN patents; the portions that do relate to the UMN patent applications only allege access to the early applications, not to the subject matter later claimed in the issued claims, and do not connect the dots to show copying. Dr. Benson admitted in his deposition that the evidence he relies on fails to show a nexus between the alleged copying by Ferring and the asserted claims. Ex. 11 at 137:8-138:24 (discussing Exhibit 12 [Benson Ex. 12]), 152:8-164:2 (discussing Exhibits 13, 14, and 15 [Benson Exs. 13, 14, and 15]).

As to the Borody patents, Dr. Benson admitted that he could not identify any feature of the asserted claims of the Borody patents that Ferring allegedly copied. Ex. 11 at 221:13-222:3, 223:7-9 ("Q. And what exactly did they copy out of the asserted claims of the Borody patents? A. I can't tell you at this point."). His reports rely on purported awareness of the parent Borody application and Dr. Borody's work. Ex. 9, ¶58; Ex. 10, ¶¶1277, 1282. Additionally, Dr. Benson recites efforts to license the Borody patents and citation to the parent Borody application in the Jones and Hlavka patents. Ex. 10, ¶¶1278-1281. He does not show nexus between Ferring's alleged copying and the asserted claims.

Ferring's experts, Dr. Britton and Dr. Savidge, addressed the alleged evidence of copying. Dr. Britton notes that Rebiotix's development of RBX2660 was complete before clinical studies started in September 2013, while the earliest Borody patent issued in November 2019. Ex. 16, ¶¶446-448. Dr. Savidge notes that the earliest UMN claim issued in April 2019. Ex. 17, ¶560. Dr. Savidge further notes that Courtney Jones, one of the individuals responsible

for developing REBYOTA (internal code RBX2660) testified that she was unaware of the UMN patent applications when RBX2660 was under development. *Id.*, ¶¶558-59, 561.

3. Legal standard

Proving infringement (including induced infringement and willfulness) is Finch/UMN's burden. *AOS Holding Co. v. Bradford White Corp.*, No. 18-412-LPS, 2021 WL 5411103, at *20 (D. Del. Mar. 31, 2021). Finch/UMN rely on Ferring's alleged copying to show the specific intent for induced infringement and willfulness and have not met their burden as to copying.

With respect to copying as it pertains to willfulness or induced infringement, there can be no copying of a patent prior to its issuance. *Gustafson, Inc. v. Intersys. Indus. Prod., Inc.*, 897 F.2d 508, 510 (Fed. Cir. 1990). In some circumstances, evidence of pre-patent copying may be relevant in determining an infringer's state of mind after the patent issued. *See DMF, Inc. v. AMP Plus, Inc.*, No. 18-cv-07090-CAS, 2023 WL 5214067, at *4 (C.D. Cal., Aug. 11, 2023). But in view of its limited relevance and high potential prejudice, purported evidence of pre-patent copying "must demonstrate 'particularly egregious behavior.'" *Sonos, Inc. v. D&M Holdings Inc.*, No. 14-1330-WCB, 2017 WL 5633204, at *4 (D. Del., Nov. 21, 2017) (Bryson, J., sitting by designation and collecting cases). This Court has followed *Sonos*'s reasoning. *Bioverativ Inc. v. CSL Behring LLC*, No. 17-914-RGA, 2020 WL 1332921, at *3 (D. Del. Mar. 23, 2020). Observing that "[c]opying a product which is not protected by the patent laws is not illegal and does not constitute infringement," *id.* at *3, this Court found that defendants' pre-patent activities did not amount to "elaborate copying" or "consciously wrongful," "malicious" behavior, and granted summary judgment of no willful infringement *id.* at *3-*4.

Copying can be a secondary consideration of non-obviousness, but only if what was copied was "the claimed invention." *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 999-1000 (Fed. Cir. 1986). To qualify as a secondary consideration, the alleged copying must also

have been undertaken because of "a nexus [to] the patented features." *Apple Inc. v. Samsung Elecs*. Co., 816 F.3d 788, 798 (Fed. Cir. 2016), *vacated in nonrelevant part on reh'g en banc*, 839 F.3d 1034 (Fed. Cir. 2016). A patentee must establish a specific "'nexus between the evidence [of secondary considerations] and the merits of the *claimed invention*,'" as opposed to the aspects of the invention that incorporate useful prior art. *Wyers v. MasterLock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quoting *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (purported evidence of copying had little weight because applicant did not "detail what aspect(s) of the invention claimed . . . was (were) targeted by industry copyists")) (emphasis in original); *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1026-1028 (Fed. Cir. 1985) (same).

4. Argument

Under the governing legal standards, Finch/UMN cannot rely on evidence of copying as a secondary consideration or to support a finding of willfulness or induced infringement.

Finch/UMN cannot meet its burden of production as to copying as a secondary consideration because it has failed to show any nexus "between the copying and the **novel aspects of the claimed invention** . . . ." *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (emphasis added). Accordingly, Finch/UMN's "evidence" is legally irrelevant. *See, e.g.*, *Leapfrog Enters., Inc. v. Fisher-Price, Inc*., No. 03-927-GMS, 2005 WL 1331216, at *1-*2 (D. Del. June 6, 2005) ("[E]vidence of copying the patentee's product is legally irrelevant unless the product is shown to be an embodiment of the claims." (cleaned up)). In *Dako Denmark A/S v. Leica Biosystems Melbourne Pty Ltd.*, 662 Fed. Appx. 990, 997-98 (Fed. Cir. 2016), the Federal Circuit affirmed a Patent Trial and Appeal Board finding of no nexus, despite the defendant's alleged access to a business plan, substantial similarity between the products, and a later patent application filed by the defendant. *Id.*; *see also In re Garrido*, 646 Fed. Appx. 942, 944 (Fed. Cir. 2016) ("[W]hile copying may be a relevant secondary

consideration . . . 'a nexus between the copying and the novel aspects of the claimed invention must exist for the evidence of copying to be given significant weight in an obviousness analysis.'" (cleaned up)). Because Finch/UMN has not shown a nexus, the Court should grant partial summary judgment in Ferring's favor as to copying as a secondary consideration.

Copying is also the basis for Finch/UMN's allegations of willfulness and induced infringement. Finch/UMN has failed to point to any evidence of copying that could support either allegation. First, Dr. Benson does not point to any specific asserted claim that was supposedly copied. At most, Dr. Benson shows only that Rebiotix was working in the same general field as UMN and Dr. Borody. Ex. 9, ¶¶51-58; Ex. 10, ¶¶1276-1283 (Borody patents), ¶¶1374-1388 (UMN patents). Second, all the evidence that Dr. Benson relies on predates the issuance of the Borody and UMN patents. In that circumstance, Finch/UMN must identify "particularly egregious behavior." *Bioverativ*, 2020 WL 1332921 at *3-*4. Dr. Benson fails to do so. *See* Ex. 11 at 125:3-25, 222:4-223:6. Dr. Benson has not identified any such "particularly egregious behavior." The Court should therefore grant partial summary judgment as to copying. Moreover, because Finch/UMN cannot support any other theory of willful infringement besides copying, under *Celotex*, the Court should grant summary judgment of no willful infringement

B. The Markush group in the asserted claims of the UMN patents is improper

1. Summary of argument

All asserted claims of the UMN patents are directed to methods of achieving specific percentage decreases in Proteobacteria (the '914 patent) or specific percentage increases in Firmicutes (the '012 patent) (the "% change limitations") in patients using compositions that include, *inter alia*, at least six different bacterial classes selected from a group of ten different bacterial classes ("the Markush group"). But "class" is a broad taxonomic level that includes numerous orders, families, genera, species, and strains. One bacterial species or strain is not

necessarily interchangeable with another, even if they fall within the same class. This lack of substitutability of one for the other is the hallmark of an improper Markush group.

2. Statement of facts

Both Ferring's expert, Dr. Treangen, and Finch/UMN's expert, Dr. Schloss, agree that, at higher taxonomic orders (*e.g.,* phylum and class) the human gut microbiome contains certain dominant taxa (including virtually all of the classes listed in the Markush group). Ex. 20 at 124:11-18; Ex. 19, ¶¶35, 49. However, they also agree that, at lower taxonomic orders (*e.g.*, genus, species, and strain), there is considerable variation in both the specific bacteria present, their relative abundance, and their functional characteristics (such as pathogenicity). Ex. 18, ¶90; Ex. 19, ¶¶ 35, 49; Ex. 20, 128:3-19, 152:16-25.

Every asserted claim of the UMN patents contains a Markush group that requires that the composition used in the methods contain at least one representative from "at least 6 different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteobacteria, Mollicutes, and Verrucomicrobiae." Ex. 5 at cls. 4, 7, 9, 18, 23; Ex. 6 at 1, 7, 9, 12. It is undisputed that the Markush group is met if there is at least one bacteria present from at least six of the enumerated classes. Ex. 20 at 100:9-13.

3. Legal standard

Markush groups are improper and indefinite if they do not provide clear notice of what is claimed. *See In re Hass*, 141 F.2d 122 (CCPA 1944); *see also In re Kiely*, 2022 WL 2062163 (Fed. Cir., June 8, 2022) (affirming Board's conclusion that claims are indefinite due to improper Markush claiming, in part because of "the breadth of variation among the specified alternatives"). A Markush group is improper "if either: (1) the members of the Markush group do not share a 'single structural similarity' or (2) the members do not share a common use." MPEP,

9th ed., rev. 07.2022, § 2117 (citations omitted). That is, the Markush group is improper if the members of the class are not "substitutable, one for the other, with the expectation that the same intended result would be achieved." *Id.* (citations omitted).

4. Argument

The propriety of the Markush group rests on the assumption that any bacterial species within a given class is functionally interchangeable with any other species in that class (or another class). *See* MPEP § 2117. Finch/UMN's own expert's testimony shows that is not the case for the UMN patents. For example, both Dr. Schloss and Dr. Treangen agree that *E. coli* (which falls within one of the ten enumerated classes) has toxigenic and non-toxigenic strains (and that these strains cannot be distinguished by the methods disclosed in the UMN patents' specification). Ex. 18, ¶69; Ex. 19, ¶34. Further, Dr. Schloss noted three different species of *Bacillus* (which fall into one of the ten enumerated classes)—*B. anthracis, B. cereus, and B. thuringiensis*—that are indistinguishable using the techniques described in the UMN patents' specification. Ex. 20 at 46:24-47:22, 49:1-4. These bacteria are not interchangeable. *B. anthracis* will kill humans, *id.* at 49:1-4; *B. cereus* suppresses plant pathogens, *id.*; and *B. thuringiensis* is a commonly used insecticide that is harmless to humans *id.* at 49:1-4, *see also* Ex. 59. Similarly, although the UMN patents' specification describes increasing "non-pathogenic Clostridia," which would exclude toxin-producing strains of *C. difficile*, the broad reference to Clostridia in the Markush group includes both non-pathogenic and toxin-producing strains. Ex. 5 at 15:9-30. Due to these functional differences across the claimed classes and the fact that the claims only require a single representative species from six of the ten enumerated classes be present (which leads to myriad potential compositions as discussed in Section III.C), the Markush group in the asserted claims of the UMN patents renders them invalid as indefinite.

Moreover, if the functionality of the Markush group is considered in the specific context

of the claims, it also clearly fails the legal test. For example, the claims of the '914 patent are all directed to decreasing Proteobacteria in individuals by required numeric percentages. *See, e.g.*, Ex. 5 at cls. 4, 9. However, three of the enumerated classes in the Markush group are Proteobacteria., *id.* at 7:52-54. Compositions in which the selection of six classes includes one or more of the classes of Proteobacteria listed in the Markush group is incompatible with the goal of decreasing Proteobacteria. Similarly, the '012 patent requires an increase in Firmicutes. However, only three of the enumerated classes (Bacilli, Clostridia, and Erysipelotrichi) are part of the phylum Firmicutes. Ex. 5 at 7:45-47. There are numerous permutations of compositions that meet the Markush group limitation that contain no Firmicutes and thus would be ineffective at increasing Firmicutes. Thus, the members of the Markush group would function differently to decrease Proteobacteria or increase Firmicutes, making the Markush group improper and rendering all asserted claims of the UMN patents invalid as indefinite.

C. The asserted claims of the UMN patents lack written description support for the % change limitation and the Markush group

1. Summary of argument

The asserted claims of the UMN patents are directed to methods of changing by specified percentages the relative abundance of the bacteria from the phyla Firmicutes and Proteobacteria ("% change limitation") by administering a stool composition that, *inter alia*, meets the Markush group. A POSA would not understand from reading the specification, which includes illegible figures, that the inventors were in possession of the claimed inventions. Both the % change limitation and the Markush group lack written description support. The only support for these limitations in the specification is from broad, nonspecific laundry lists and the data generated from a single patient/donor pair described in Example 1 and its corresponding illegible figures. Further, because the claims only require that a single bacterial representative from each of six

classes be present, the claims encompass myriad permutations. No reasonable fact finder could find that the inventors were in possession of the claimed limitations.

2. Statement of facts

The only taxonomic data in the UMN patents' specification is in Example 1. *See generally*, Ex. 5. The text of Example 1 does not describe or discuss seven of the ten classes in the Markush group nor does it provide information about changes in the relative abundances of Firmicutes and Proteobacteria. *Id.* at Example 1. Figures 1 and 2 associated with Example 1 represent only a single donor/patient pair and are illegible. *Id.* at Fig. 1, 2; Ex. 22 at 118:10-12; Ex. 23 at 259:7-13 (discussing a color version of the figures); Ex. 24 at 122:9-13, 124:14-16; Ex. 25 at 326:4-23, 333:12-334:12; Ex. 20 at 209:11-14, 219:25-220:5. The only other written description for the % change limitation and the Markush group are in columns 5, 7, and 15 and these provide no guidance and do not show that the inventors were in possession of the invention actually claimed. Ex. 5 at 5:19-29; 7:37-8:19, 15:21-52.

3. Legal standard

The written description requirement contained in 35 U.S.C. § 112 requires that the patent's disclosure "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). As here, when a drawing or figure is unreadable, even to the inventor, it cannot provide written description support. *Minemyer v. B-Roc Reps., Inc.*, 695 F.Supp.2d 797, 804-05 (N.D. Ill. 2017) (finding that the drawing did not pass the "eye test" because even the inventor could not determine if it showed the claimed taper).

4. Argument

The only example in the UMN patents' specification that includes any analysis of the donor or recipient's microbial composition is Example 1, which is limited to a single

donor/patient pair. *Id.* The text of Example 1 mentions only three of the ten classes in the asserted claims (Mollicutes, Gammaproteobacteria, and Clostridia). *Id.* at Example 1. Further, Example 1 provides no information on the percentage decreases in Proteobacteria (as required by the asserted claims of the '914 patent) or the percentage increases in Firmicutes (as required by the asserted claims of the '012 patent). The only data regarding that information is in Figures 1 and 2—which is illegible as confirmed by the inventors and both parties' experts. Ex. 22 at 142:13-25; Ex. 23 at 249:8-250:8; Ex. 24 at 121:2-7; Ex. 25 at 332:21-333:4; Ex. 20 at 122:5-123:15. This is true despite Drs. Hamilton and Sadowsky reviewing color versions of the figures, which are not available in the patent or to the public. Ex. 22 at 125:8-12, 126:9-17, 130:25-133:19, 135:13-142:25; Ex. 23 at 249:20-25. Because the figures are illegible they do not provide written description support for the Markush group or the required changes in Proteobacteria and Firmicutes. *See Minemyer*, 695 F.Supp.2d at 804-05.

The rest of the specification provides no additional support to show that the inventors were in possession of the asserted claims. Rather, in various places it recites that embodiments of the alleged inventions can contain from 1 to 10 phyla, from 1 to 10 classes, or from 10 to over 400 species. Ex. 5 at 5:19-29; 7:37-8:19. Similarly, the patent describes increasing the relative abundance of Firmicutes in ranges from at least 5% to at least 50% and decreases in Proteobacteria ranging from at least 10% to at least 40%, although both are "in the recipient's colon." *Id.* at 15:21-52. The corporate witness on the UMN patents (named inventor Dr. Khoruts) admitted that the data supporting (i) the Markush group limitation, (ii) the percentage decrease in Proteobacteria, and (iii) the percentage increase in Firmicutes came from Example 1 and that it could not be statistically significant, because one cannot do statistics on data derived from a single patient. Ex. 24 at 145:10-148:3. Dr. Khoruts testified that there was some additional work

from a paper published in 2013, but it was not in the specification and was not "fully completed" when the patent was filed, *id.* at 149:21-150:1, and therefore not knowable to a POSA.

Moreover, given that the Markush group requires only a single representative from each of six of the ten enumerated classes be present, conservatively there are 210 different potential compositions claimed, assuming, *inter alia*, that any bacterial strain from the class is acceptable. Ex. 21, ¶89. Even limiting the bacterial species to just those that were known to exist in the human gut (again discounting the differences in strains) as of approximately 2013, there are over three billion different permutations. *Id.*, ¶91. More realistic assumptions (still assuming that any species or strain is acceptable) results in trillions of compositions. *Id.*, ¶92. Thus, there are myriad variations for the composition claims. The specification does not demonstrate that the inventors were in possession of the full range (or even a small minority) of permutations, further showing that the asserted claims of the UMN patents lack written description and are invalid.

This Court's recent ruling in *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, No. 19-1727-RGA, 2023 WL 6295496, at *12 (D. Del. Sept. 27, 2023), particularly FF7-FF12, is on all fours. The UMN patents claim any combination of any bacteria falling within at least six of the ten classes listed, but the specification does not disclose all of those combinations. *See generally* Ex. 21, ¶¶135-146.

D. Finch/UMN is barred from asserting that the particle size limitations are met under the doctrine of equivalents and Finch/UMN cannot demonstrate literal infringement of the particle size limitations

1. Summary of argument

Each asserted claim of the UMN patents contains a particle size limitation. Dr. Benson opined on infringement of these claims inferentially, not based on actual testing. *See, e.g.,* Ex. 9 ¶¶356-59. [redacted] but provides two different theories for why REBYOTA

meets the particle size limitations under the doctrine of equivalents ("DOE")—one in his opening report and a new theory in reply. Dr. Benson's theories of equivalence are barred by prosecution history estoppel ("PHE"), improperly focus on the claim as a whole in determining equivalence and vitiate the particle size limitations. The Court should grant summary judgment of no infringement based on DOE. Further, Finch/UMN has failed to show literal infringement, and the Court should also grant summary judgment of no literal infringement.

2. Statement of facts

The asserted claims of the '012 patent and claims 18 and 23 of the '914 patent require that the composition or extract contain "no particle having a size of greater than 0.5 mm" and claim 7 of the '914 patent requires that the composition is "capable of passing through a 0.5 mm sieve" ("the particle size limitations"). The term "no particle having a size of greater than 0.5 mm" means "no particle greater than 0.5 mm as shown by sieving." (D.I. 142 at 3.)

During prosecution of the '012 patent application, the original independent claim had no limitation regarding particle size, but one of the dependent claims had a limitation wherein the "preparation consists essentially of particles capable of passing through a 0.5mm sieve . . . ." Ex. 27 at FINCH_UMN_0009753-54 (cls. 43, 55). The examiner rejected the originally filed claims on numerous grounds, including obviousness over the prior art. *See generally*, Ex. 28. After an applicant-initiated interview where the applicant and examiner discussed the draft claims, the applicant amended the claims, including adding the limitation "no particle having a size of greater than 0.5 mm" and adding a dependent claim including "particles capable of passing through a 0.5 mm sieve" Ex. 29 at FINCH_UMN_0010725, -727, -729, -748-57.

The original independent claim of the '914 patent application had no limitation regarding particle size, but one of the dependent claims required that the "preparation consists essentially of particles capable of passing through a 0.5mm sieve," Ex. 30 at FINCH_UMN_0007350 (cls.

43, 54), and faced an obviousness rejection, Ex. 31 at FINCH_UMN_0007552-65. In response, applicants amended their claims to add a new independent claim with a limitation "wherein said fecal extract or preparation is capable of passing through a 0.5 mm sieve . . . ." Ex. 32 at FINCH_UMN_0007940 (cl. 71). In a later interview, applicants agreed to amend the original independent claim by adding "said human fecal extract comprises no particle having a size of greater than 0.5 mm." Ex. 33 at FINCH_UMN_0007956, -959.

In his opening report, Dr. Benson opined that REBYOTA literally meets the particle size limitations because [redacted]. *See, e.g.*, Ex. 9, ¶¶355-59. Alternatively, Dr. Benson argues that the particle size limitations are met equivalently [redacted]. *See, e.g.*, *id.*, ¶¶360-62. Dr. Benson's opinions for why REBYOTA meets the "capable of" term are substantively the same as his arguments for why the "no particle" limitations are met. *See, e.g.*, *id.*, ¶¶381-82 (incorporating paragraphs 354-63 regarding "no particle having a size of greater than 0.5 mm" and providing no new substantive argument). Ferring produced samples of REBYOTA to Finch/UMN, but their expert Dr. Benson did not test (or even look at) those samples and instead bases his infringement analysis solely on circumstantial evidence. *See, e.g.*, i*d.*, ¶¶354-63, 381-83, 476-85; Ex. 34, ¶¶133-62.

In contrast, Ferring's expert, Dr. Johnson, tested three doses of REBYOTA from the same batches of REBYOTA produced to Finch/UMN. Ex. 26, ¶76. Dr. Johnson's testing showed that [redacted]. Ex. 26, ¶94; Ex. 35; Ex. 36. This demonstrated that there is no literal infringement.

In reply, Dr. Benson newly asserted [redacted]

[redacted] *See, e.g.*, Ex. 34, ¶¶147-48. His analysis focuses on the fecal preparation or extract as a whole, not the individual particles, *see, e.g.*, Ex. 9, ¶362; Ex. 34, ¶¶149-52, and Dr. Benson asserts that focusing any DOE analysis on the "'particles,' as opposed to the fecal microbe preparation or fecal extract which the particles comprise," is improper. *See, e.g.*, Ex. 34, ¶150. Dr. Benson admitted at deposition that he does not put an upper limit on the size of the particles that he would deem equivalent to the 0.5 mm particle size limitation. Ex. 11 at 181:25-182:5. [redacted]

3. Legal standard

If a product or method does not literally meet all limitations of a claim it may still infringe under the DOE if it contains an element that is equivalent to the missing limitation. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21, 39-40 (1997). The DOE is "applied to individual elements of the claim, not to the invention as a whole." *Id.* at 29. Further, "it is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." *Id.*

Prosecution history estoppel ("PHE") prevents "a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution. Prosecution history estoppel can occur in two ways: either (1) by making a narrowing amendment to the claim (amendment-based estoppel) or (2) by surrendering claim scope through argument to the patent examiner (argument-based estoppel). *Pharma Tech Sol'ns, Inc. v. LifeScan, Inc.*, 942 F.3d 1372, 1380 (Fed. Cir. 2019) (cleaned up). PHE also limits the

scope of the DOE "when an amendment is made to secure the patent and the amendment narrows the patent's scope." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002). "Whether prosecution history estoppel applies to limit the doctrine of equivalents is a question of law . . . ." *Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368, 1375 (Fed. Cir. 2020) (cleaned up). Where a narrowing amendment is made to incorporate the limitation found in a dependent claim into an independent claim, a presumption arises that the applicant surrendered the subject matter between the original and amended claim limitation. *See Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1305 (Fed. Cir. 2005). "To prove literal infringement, the patentee must show that the accused device [or process] contains each and every limitation of the asserted claims." *SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 983 F.3d 1367, 1380 (Fed. Cir. 2021) (cleaned up).

4. Argument

Dr. Benson's DOE arguments for the particle size limitations fail as a matter of law because they: (i) are barred by PHE, (ii) improperly focus on the claim as a whole in determining equivalence, and (iii) vitiates the particle size limitations. Summary judgment of no literal infringement is also proper as there is no genuine dispute that REBYOTA has particle sizes larger than 0.5 mm.

a. Dr. Benson's analysis is barred by PHE

PHE bars Finch/UMN from arguing infringement under the DOE for the particle size limitations, which are limitations in all asserted claims of the '914 and '012 patents. The applicant surrendered particles larger than 0.5 mm by making narrowing amendments during prosecution and adding limitations regarding particles no larger than 0.5 mm. *See Pharma Tech.*, 942 F.3d at 1380 (noting that narrowing amendments can result in PHE).

When prosecuting the '012 patent, in response to a rejection, the applicants amended the

claims to add a limitation of "no particle having a size of greater than 0.5mm" and rejoined a dependent claim reciting "wherein said human fecal preparation consists essentially of particles capable of passing through a 0.5 mm sieve and the human fecal donor's intestinal microbiota." Ex. 29 at FINCH_UMN_0010724-27, -729, -754-55, -757. When prosecuting the '914 patent, in response to a rejection, the applicants amended the claims to add a limitation of "no particle having a size of greater than 0.5 mm." Ex. 33 at FINCH_UMN_0007956. Both amendments ultimately resulted in allowances and thus the presumption of estoppel applies. *See Festo*, 535 U.S. at 736. Thus, PHE bars DOE for the "no particle having a size of greater than 0.5 mm" limitation in the asserted claims of the '914 and '012 patents.

Finch/UMN is additionally barred from arguing the doctrine of equivalents for the "capable of passing through a 0.5 mm sieve" limitation of the '914 patent because it narrowed its claim from a dependent claim to part of an independent claim. When prosecuting the '914 patent, the applicant originally included a limitation regarding particles capable of passing through a 0.5mm sieve solely as part of a dependent claim. Ex. 30 at FINCH_UMN_0007350 (cl. 54). In response to a rejection, the applicants later added in this limitation to an independent claim. Ex. 32 at FINCH_UMN_0007938, -940 (canceling cl. 54 and adding cl. 71). Thus, Finch/UMN is barred from trying to recapture what it disclaimed under a DOE analysis of the "capable of passing" limitation. *See, e.g., Biagro*, 423 F.3d at 1305 ("If the narrowing amendment was the addition of a new claim limitation, as in the case before us, equivalents are presumptively not available with respect to that limitation.").

Finch/UMN cannot overcome the presumption by demonstrating any exception, especially in light of explicit arguments made in prosecution of the parent application regarding the relevance of the particle size. *See, e.g., Pharma Tech*, 942 F.3d at 1381 ("The inventors'

clear statements not only establish argument-based estoppel, but also negate [the patentee's] reliance on the tangential relation exception"); *see also Augustine Med. Inc. v. Gaymar Indus. Inc.*, 181 F.3d 1291, 1300 (Fed. Cir. 1999) ("Because the prosecution history of a parent application may limit the scope of a later application using the same claim term . . . these claim amendments and arguments restrict the scope of the claims in each of the later issued patents . . ."). In prosecuting the parent of both the '012 and '914 patents, the applicants made the relevance of the particle size limitation to patentability explicit: "The Examiner has not shown where the cited references alone or combined provide for particles of non-living material, let alone no particles of non-living material having a size of greater than 0.5mm." Ex. 37 at PDF page 85. This concession was not isolated, demonstrating its materiality. *See, e.g.,* Ex. 38 at PDF page 14.

Thus, amendment-based estoppel applies. Applicants' amendments triggered a presumption of estoppel, and given their own statements, that presumption cannot be rebutted.

b. Dr. Benson's DOE analysis is flawed because it focuses on the claim as a whole, not the particle size limitations

Dr. Benson's DOE analysis is flawed for an additional reason: the proper inquiry is whether the size of the particles found in REBYOTA are insubstantially different or function in the same way to achieve the same result as the claimed particle sizes. But Dr. Benson does not analyze the DOE element-by-element, instead improperly focusing on the fecal preparation as a whole. *See, e.g.*, Ex. 9, ¶362; Ex. 34, ¶¶149, 152; *see also* Ex. 34, ¶150 (arguing that focusing on the function of the "particles" rather than the function of "the fecal microbe preparation or fecal extract which the particles comprise" is an improper analysis of the DOE for the particle size limitations). Dr. Benson opines that the particle size limitation is met because REBYOTA "perform[s] the same function in the same way to achieve the same clinical outcome." *See, e.g.*, Ex. 9, ¶362. Specifically, Dr. Benson asserts that "REBYOTA provides a fecal donor's intestinal

microbiota that meets the specifications of the claim, as discussed above, by administration of the composition via an enema, to achieve the result [claimed in the asserted claims]." *See, e.g.*, *id.*, ¶362. Dr. Benson provides the same argument in reply, [redacted] *See, e.g.* Ex. 34, ¶¶142-52.

[redacted] In doing so, Dr. Benson attempts to sidestep a DOE analysis on the particle size limitations. Dr. Benson has no "hard data" to support his assertion that the particles in REBYOTA are equivalent to the particle size claimed: according to Dr. Benson, such data is unnecessary because "the Rebyota product works with or without." Ex. 11 at 182:6-25. Because Dr. Benson does not analyze the DOE based on the particle size limitations, summary judgment of no DOE should be granted. *See Warner-Jenkinson*, 520 U.S. at 29.

c. Dr. Benson's DOE analysis vitiates the claim and also establishes lack of literal infringement

Dr. Benson's arguments also vitiate the "no particle having a size of greater than 0.5 mm" limitation and establish that both particle size limitations are not literally infringed. The claims explicitly require that "no" particle is larger than 0.5 mm. No means none, but Dr. Benson's analysis reads out this limitation. He offers no evidence that REBYOTA does not include some particles greater than 0.5 mm. Similarly, Dr. Benson does not rebut Dr. Johnson's [redacted].

Instead, Dr. Benson asserts that "[redacted]." Ex. 9, ¶358; *see also* Ex. 34, ¶147 (assuming without empirical support that, while "[redacted]

[redacted] He further asserts that particles larger than 0.5 mm are equivalent to particles smaller than 0.5 mm because larger particles "far exceed[] the size of the individual species of bacteria." Ex. 9, ¶362; Ex. 34, ¶148 (arguing that composition would be the same if it included "a small number of particles of or around 1 mm in size"); *see also* Ex. 34, ¶151. Tellingly, during his deposition, Dr. Benson admitted that there is no upper limit on the size of particles that he "would deem biologically equivalent" to the particle size limitations in the claim. Ex. 11 at 181:25-182:5. Dr. Benson's DOE argument effectively eliminates the particle size limitations—any size particle can be present just as long as the accused product clinically works. This is contrary to the law. As the Federal Circuit has recently held, "the doctrine of equivalents cannot be used to effectively read out a claim limitation, because the public has a right to rely on the language of patent claims." *Duncan Parking Techs., Inc. v. IPS Group, Inc.*, 914 F.3d 1347, 1362 (Fed. Cir. 2019) (holding that defendant's DOE argument improperly required vitiating a claim limitation) (cleaned up). *See also Warner-Jenkinson*, 520 U.S. at 29. Nor can Dr. Benson demonstrate literal infringement where there is an unmet claim limitation. *SIMO Holdings*, 983 F.3d at 1380. The Court should enter summary judgment of no infringement.

E. The asserted claims of the UMN patents are invalid because the "extract" terms lack written description support

1. Summary of argument

The Court construed "extract" in the asserted claims of the UMN patents to mean "a substance obtained from a material, mixture, organism, or part of an organism by some chemical and/or physical process." (D.I. 145 at 2.) Finch/UMN's expert Dr. Schloss testified that the filtration, centrifugation, and resuspension steps described in Examples 3 and 4 of the UMN patents' specification were necessary to understand and limit the scope of the claims. Because

the "extract" terms, as construed, are broader than Examples 3 and 4, the asserted claims lack written description support. In the alternative, the Court should amend its construction of "extract" to preserve the validity of these claims.

2. Statement of facts

Ferring argued during claim construction that the "extract" terms in the UMN patents should require filtration and centrifugation, which Finch/UMN argued was improper and which the Court rejected. (D.I. 148 at 85:11-21, 86:18-22, 95:2-17, 110:7-13.) Dr. Schloss testified that (i) the asserted claims of the UMN patents are directed to "the method of processing a fecal sample" which is "exactly what's" disclosed in Examples 3 and 4 and (ii) they must be coupled with the screening protocol in Example 2 to achieve the claimed microbial changes and ensure that the Markush group limitation is met. Ex. 20 at 191:21-192:25, 193:8-25.

3. Legal standard

The standard for written description under Section 112 is set forth in Section III.C.3.

4. Argument

Dr. Schloss testified that the asserted claims of the UMN patents are supported because the methods claimed are limited by the screening steps in Example 2 (to ensure a healthy donor) and the processing steps in Examples 3 and 4, such that the outcome of those steps is that one will have six of the ten classes (as required by the Markush group) and will decrease Proteobacteria or increase Firmicutes as required by the claims. Ex. 20 at 191:21-192:25, 193:8-25; *see also id.* at 103:5-104:14, 104:24-105:24, 172:11-22. Dr. Schloss has read Examples 2, 3, and 4 into the claims to assert that the Markush group is proper and supported. The screening protocols (Example 2) are not in the asserted claims. Examples 3 and 4 teach a processing technique of homogenizing, filtering, washing (centrifuging and pouring off the supernatant), and resuspending. Ex. 5 at Examples 2, 3, and 4. Dr. Schloss's position is the same position that

Ferring argued during claim construction, *compare* Ex. 20 at 191:21-192:25, 193:8-25 *with* D.I. 91 at 62-65, 68-70, and which the Court rejected. However, Dr. Schloss's opinion is consistent with testimony from Drs. Hamilton, Sadowsky, and Khoruts, who each testified that their invention was the process used to make the pharmaceutical composition, which is described in Examples 3 and 4 and requires filtration and centrifugation. Ex. 22 at 153:18-156:12, 175:8-19; Ex. 23 at 26:2-21, 27:4-28:5; Ex. 24 at 180:5-181:6. This is also consistent with Ferring's expert Dr. Johnson's opinion that a POSA would understand that "extract" requires filtration and centrifugation. Ex. 26, ¶¶71-73, 241-44.

Thus, three of the named inventors of the UMN patents and experts for both parties have opined that a POSA would read the asserted claims to require filtration and centrifugation. However, Finch/UMN reads the Court's construction—"a substance obtained from a material, mixture, organism, or part of an organism by some chemical and/or physical process"—as significantly broader than the disclosures in the UMN patents' specification (which only teach methods of manufacture that involve filtration and centrifugation). Under Finch/UMN's interpretation, "extract" is significantly broader than how three of the named inventors and experts from both sides indicate they interpret the term based on the specification. Thus, the claims are invalid for lack of written description. *MHL Custom, Inc. v. Waydoo USA, Inc.*, 654 F.Supp.3d 329, 342-45 (D. Del. 2023) (claims that encompassed stable and unstable watercraft lacked written description support as the specification indicated stability was necessary).

In the alternative, to preserve the validity of the claims, the Court should revise its construction of this term and adopt the construction initially proposed by Ferring. *See Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1384 (Fed. Cir. 2001) (claims amenable to more than one construction should be construed to preserve their validity).

F. Summary judgment of noninfringement of the asserted claims of the '702, '309, and '193 patents is appropriate because REBYOTA's FDA-approved use is not "treatment"

1. Summary of argument

All asserted claims of the '702, '309 and '193 patents require some aspect of treating CDI. *See, e.g.*, Ex. 1 at cl. 11; Ex. 2 at cl. 12 ("amount effective for treating recurrence of *C. difficile* infection"); Ex. 3 at cl. 1 ("the method preserves a number of viable bacteria from the stool sufficient to overcome a *Clostridium difficile* infection in a patient"); Ex. 3 at cl. 14 ("to restore deficient fecal flora in a patient with a *Clostridium difficile* infection") (collectively, the "treatment" limitations). However, REBYOTA is only approved to prevent recurrent CDI ("rCDI"), not for treating CDI. As these terms are used and understood by the patentee, the FDA, and the American College of Gastroenterology's ("ACG") CDI guidelines, "treating" and "preventing" are mutually exclusive. Therefore, REBYOTA cannot infringe the "treating" limitations as a matter of law.

2. Statement of facts

The REBYOTA label states that REBYOTA is indicated "for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI." Ex. 39 at FER_RBX02700270-71. The label includes a "Limitation of Use" stating that, "REBYOTA is **not** indicated for **treatment** of CDI." *Id.* (emphasis added). This is not disputed. Ex. 40, ¶58; Ex. 43 at 118:25-119:3 Ex. 41, ¶46.

In addition, the ACG has published guidelines titled "ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of *Clostridioides difficile* Infections," on which Finch/UMN's expert Dr. Stollman is the last named author. Ex. 42. These guidelines distinguish prevention of rCDI from treatment of rCDI. Ex. 42 at Table 2, FER_RBX00239402, -406; Ex. 43 at 137:1-138:12, 140:11-142:5. Specifically, the ACG Guidelines recommend antibiotics, not

fecal microbiota transplantation ("FMT"), for treatment of rCDI. Ex. 42 at FER_RBX00239406; Ex. 43 at 142:9-11, 144:10-145:8. Separately, under a heading titled "Prevention of CDI Recurrence," FMT is recommended. Ex. 42 at FER_RBX00239406; Ex. 43 at 145:23-146:3. REBYOTA is a form of FMT. Ex. 43 at 25:25-26:9.

During prosecution of the '702 patent, claims relating to "preventing recurrence of CDI" were introduced but, following an examiner interview, were changed to "treating." *See* Ex. 43 at 163:3-168:12, Ex. 44 at FINCH_UMN_0011458, -461, -468, -470. Further, the Borody patents' specification repeatedly distinguishes between treatment and prevention. *See e.g.*, Ex. 2 at 16:64-17:9. Thus, the applicant recognized a difference between treating and preventing rCDI.

3. Legal standard

Summary judgment of noninfringement is permissible where the accused infringer, Ferring, makes a showing that the patentee, Finch, cannot satisfy its burden of proof. *See Celotex*, 477 U.S. at 317-18.

4. Argument

Here, summary judgment of noninfringement of the asserted claims of the '702, '309 and '193 patents is appropriate because the FDA-approved language in the REBYOTA label does not extend to "treating" CDI.

In the specification and during prosecution of the '702 patent, the applicant recognized a distinction between "treating" and "preventing" CDI. During prosecution of the '702 patent, the applicant proposed claim amendments for discussion with the examiner where the applicant sought claims directed to "preventing recurrence of *C. difficile* infection" (*see, e.g.,* claim 54). Ex. 44 at FINCH_UMN_0011458. However, subsequent to the interview with the Examiner, the applicant instead submitted a claim directed to "treating recurrence of *C. difficile* infection" (proposed claim 54, which issued as asserted claim 11), rather than "preventing recurrence of *C.*

difficile infection." *Id.* at FINCH_UMN_0011468; Ex. 1 at cl. 11. The specification also distinguishes between "treating" CDI and "preventing" CDI. *See, e.g.*, Ex. 1 at 16:57-17:2. The applicant clearly understood the distinction between "treating" and "preventing."

This distinction between "treating" CDI and "preventing" rCDI as delineated in the intrinsic evidence is confirmed by real world evidence directed to medical practitioners focused on the care of patients suffering from CDI and rCDI. The ACG Guidelines, of which Finch/UMN's expert Dr. Stollman is the last author, differentiate "Treatment of CDI" versus "Prevention of CDI Recurrence." Ex. 42 at FER_RBX00239402, -406. Under "Treatment of CDI, " the ACG Guidelines recommend antibiotics, not FMT; under "Prevention of CDI Recurrence," FMT is recommended. *Id.*

The FDA approved REBYOTA for a single indication directed to "the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI." Ex. 39 at FER_RBX02700270-71. The FDA required that a "Limitation of Use" be included in the REBYOTA label which specifically states, "REBYOTA is **not** indicated for **treatment** of CDI." *Id.* (emphasis added). Thus, as a matter of law, REBYOTA cannot infringe the "treating" limitations of the '702, '309 and '193 patents.

G. The term "substantially entire microbiota" is indefinite

1. Summary of argument

The term "substantially entire microbiota" (the "SEM term") appears in claim 11 of the '702 and is indefinite, rendering the claim invalid. Finch/UMN's expert has testified that whether a particular composition includes the "substantially entire microbiota" (i) is subjective, (ii) based on the intent of the alleged infringer, and (iii) does not have an objectively determined threshold.

2. Statement of facts

The specification of the '702 patent characterizes "entire (or substantially entire)

microbiota" in three instances. Ex. 1 at 7:63-8:2 ("wherein a substantially isolated or a purified fecal flora or entire (or substantially entire) microbiota is (comprises) an isolate of fecal flora that is at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, 99.5%, 99.6%, 99.7%, 99.8% or 99.9% isolated or pure, or having no more than about 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8%, 0.9% or 1.0% or more non-fecal floral material"), 10:17-24, and 13:28-35.

During claim construction, Ferring proposed a construction of the SEM term that tracked these passages in the specification. (D.I. 91 at 40, 42-43.) The Court rejected Ferring's argument and determined that no construction of this term was necessary. (D.I. 145 at 2.) During the claim construction hearing, the Court specifically noted that it was deferring the issue of indefiniteness. (D.I. 148 at 78:8-11.) Ferring now moves for a determination of indefiniteness.

3. Legal standard

Section 112 requires that "a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Insts., Inc*., 572 U.S. 898, 910 (2014); *see also* 35 U.S.C. § 112. A claim term "is indefinite if its language 'might mean several different things and no informed and confident choice is available among the contending definitions.'" *Media Rts. Techs., Inc. v. Cap. One Fin. Corp*., 800 F.3d 1366, 1371 (Fed. Cir. 2015).

When a question of indefiniteness relates to a term of degree, such as "substantially," "the patent must provide 'some standard of measuring that degree' such that the claim language provides 'enough certainty to one of skill in the art when read in context of the invention.'" *In re Mobile Telecomms. Techs., LLC*, 265 F. Supp. 3d 454, 474 (D. Del. 2017) (citation omitted). "[T]erms of degree render a claim indefinite where the intrinsic evidence (or extrinsic evidence, where relevant and available) provides insufficient guidance as to any objective boundaries for the claims." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1348 (Fed. Cir.

2022). "Indefiniteness is a question of law" appropriate for summary judgment. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.,* 845 F.3d 1357, 1370 (Fed. Cir. 2017).

4. Argument

During prosecution of the '702 patent's parent application, the examiner considered the use of "substantially" in the context of the invention(s) described in the specification. A proposed independent claim included both the SEM term and "substantially devoid of fiber." Ex. 60 at FINCH_UMN_0003924. The examiner determined the phrase "substantially devoid of fiber" rendered the claim indefinite, but that the SEM term did not. The examiner's reasoning was based on the guidance regarding the numerical ranges for the SEM term provided in the specification recited above ("Page 9" of the specification, as referenced by the examiner, corresponds to Ex. 1 at 7:63-8:2). Ex. 61 at FINCH_UMN_0003943; Ex. 62 at FINCH_UMN_0005684; Ex. 53 at FINCH_UMN_0000055-56. Thus, claim 11's use of the SEM term while requiring that the microbiota be "separated from rough particulate matter" (rather than "substantially devoid of fiber") is consistent with the examiner's observations from the prosecution of that related application. (*See* Ex. 63 at FINCH_UMN_0005731, -735 (amending claims in related application in response to examiner's determination that "substantially devoid of fiber" was indefinite.) In other words, without being anchored to the passages from the specification quoted above, the examiner recognized that "substantially" is indefinite.

While the Court determined that the above-cited passages are not definitional, "the patent must provide 'some standard of measuring that degree' such that the claim language provides 'enough certainty to one of skill in the art when read in context of the invention.'" *In re Mobile Telecomms.*, 265 F. Supp. 3d at 474. Ferring's expert, Dr. Kraft, has opined to precisely that effect regarding the above-quoted passages. Ex. 45, ¶¶37-48; Ex. 46, ¶¶6-16. At the same time, both counsel for Finch/UMN and Finch/UMN's expert, Dr. Mazmanian, have acknowledged that

"substantially entire" is "not a scientific term," (D.I. 148 at 65:1-6), and "that substantially entire microbiota is not a term used in the industry," Ex. 47 at 164:15-165:19. Therefore, any guidance as to its meaning must come from the patent itself.

Dr. Mazmanian has suggested that "each of [the above-cited] passages [from the specification] provides percentages of fecal flora that give guidance from a numerical perspective what constitutes the 'substantially entire microbiota,'" Ex. 48, ¶119, but has steadfastly refused to indicate what numerical range would constitute the "substantially entire microbiota," *see, e.g.*, Ex. 47 at 109:19-111:10. Even using his nebulous understanding of this term, Dr. Mazmanian's opinions have proven to be self-contradictory. For example, on the one hand Dr. Mazmanian testified that, in the abstract, "to satisfy the terminology of substantially entire microbiota in the context of the claim, which is the way I viewed the material, you would have to have more than 50 percent of the organisms." *Id.* at 121:22-122:12. But on the other hand, when considering an example in which just 10 percent of the organisms were retained, Dr. Mazmanian testified that this would still constitute the "substantially entire microbiota." *Id.* at 131:22-132:20. Dr. Mazmanian arrives at this contradictory conclusion because his opinion is that whether or not the SEM term is infringed is not an objective threshold but instead requires ascertaining the intent of the putative infringer. *Id*. at 123:16-24 ("Q. You cannot come up with a precise numerical number that's needed to satisfy the substantial[ly] entire micro[biota], correct? . . . A. I don't think there is a precise numerical number. I don't think that's how the claim should be viewed or the claim should be intended to be viewed."); *see also id.* at 131:22-132:20. This is the very definition of indefiniteness. *See DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1260 (Fed. Cir. 2014) ("When a claim term depends solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the invention, without

sufficient guidance in the specification to provide objective direction to one of skill in the art, the term is indefinite.") (cleaned up). Accordingly, the SEM term is indefinite as a matter of law and the Court should enter partial summary judgment.

H. The Borody patents are unpatentable under 35 U.S.C. § 101

1. Summary of argument

All asserted claims of the Borody patents are directed to a natural product: a human fecal microbiome preparation. None of the additional limitations in any of the claims changes this. Although Finch/UMN and its experts characterize the alleged "invention" as a pharmaceutical product formulated for enema delivery, all of the claimed processing steps and added excipients are routine and conventional and do not alter the physical characteristics and makeup of the fecal microbiome preparation. Indeed, none of the claimed excipients are even required to be in an amount effective to do anything. Additionally, the claimed processing, packaging and storage limitations are all conventional and well-known.

2. Statement of facts

The asserted claims of the '702, '309 and '080 patents are product claims, while the asserted claims of the '193 patent cover a method of manufacturing the same product. Ex. 7.

The asserted claims of the '702, '309, and '193 patents are directed to a fecal microbiome preparation used to treat rCDI (the asserted claims of the '080 patent do not mention the intended use). *See* Ex. 7. In varying combinations and levels of detail, the asserted Borody patent claims also include a standard enema delivery system, a cryoprotectant, an antioxidant, and saline—though none of these add-ons are required by the claims to perform any function or change the properties of the fecal flora. *Id.* The claims also include conventional processing steps—homogenizing and filtering and well-known transport and packaging limitations, such as delivering a non-frozen sample to be processed and packaged in an oxygen resistant bag. *Id.*

Although Finch/UMN contends that the cryoprotectant, in particular, is necessary to ensure the viability of the fecal flora during freezing and storage, Ex. 48, ¶ 50, none of the asserted Borody claims identify any function to be performed by the cryoprotectant, *see, e.g.*, Ex. 7. Additionally, Finch/UMN has introduced no evidence or testimony that the addition of **any unspecified amount** of cryoprotectant would result in a shift from too little viable fecal flora, post-freezing, to an "amount [of fecal flora] effective" for preventing rCDI. In fact, the undisputed evidence demonstrates that even when no cryoprotectant is used, an "amount [of fecal flora] effective" for preventing rCDI remains in the stool extract. Ex. 49, ¶¶82-83, 89; *see also* Ex. 50, ¶17, Ex 51. Exhibit 51 is a report published in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION concerning a randomized clinical trial which concluded that: "[a]mong adults with recurrent or refractory CDI, the use of frozen compared with fresh FMT did not result in worse proportion of clinical resolution of diarrhea." Ex. 51 at FER_RBX03012341. The frozen stool samples were mixed only with bottled water. *Id.* at FER_RBX03012342, -343.

3. Legal standard

Section 101 defines patent-eligible subject matter. 35 U.S.C. § 101. In *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208 (2014), the Supreme Court reaffirmed the framework laid out in *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc*., 566 U.S. 66, 71 (2012) "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 573 U.S. at 217. There is a two-step process for analyzing patent-eligible subject matter. *Id.* at 217-218, 221-222*; see also ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280, 1282, 1285-86 (Fed. Cir. 2023).

4. Argument

a. *Alice* step one: The Borody patents are "directed to" a natural product

The asserted claims of the Borody patents are all directed to a product of nature: a human fecal microbiome preparation (also referred to as the "microbiota of a stool sample" or "fecal bacteria," depending on the claim). Natural phenomena, or products of nature, are not patentable subject matter. *Alice*, 573 U.S. at 216-17. If a claim includes a "nature-based product that does not exhibit markedly different characteristics from its naturally occurring counterpart in its natural state, then the claim recites a 'product of nature'" under *Alice* step one. MPEP § 2106.04(c); *see also ChromaDex*, 59 F.4th at 1283-85. Here, the fecal flora in the claimed pharmaceutical preparations do not exhibit markedly different characteristics from their naturally occurring counterparts. Ex. 49, ¶71. Just as the claims in *ChromaDex* broadly read onto milk and its properties, the asserted claims of the Borody patents read onto fecal flora from a human stool sample and its properties. *See ChromaDex*, 59 F.4th at 1282-83.

b. The Borody patents fail under *Alice* step 2

Because the claims are directed to a product of nature, they fail under *Alice* step one and the analysis shifts to step two to determine whether the claims include an "inventive concept," that is "an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Alice*, 573 U.S. at 217-18 (brackets omitted). A number of the additional limitations focus on homogenization and filtration of the stool sample. This does not suffice. Isolation of the fecal flora from the stool sample, *e.g.,* via filtration, does not alter the fact that the claims are "directed to" this natural phenomenon and law of nature. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013) ("separating that gene from its surrounding genetic material is not an act of invention"). Similarly, in *ChromaDex*, the Federal Circuit noted that the claims at issue were "very broad and read on milk with only one difference," that the naturally occurring nicotinamide riboside ("NR") was isolated. *ChromaDex*, 59 F.4th at 1283-84. The

court concluded, "[T]he act of isolating the NR by itself, no matter how difficult or brilliant it may have been (although the specification makes clear that it was conventional), similarly does not turn an otherwise patent-ineligible product of nature into a patentable invention." *Id*. at 1286.

Similarly, here, fecal flora in the stool sample is separated from other "rough particulate matter," using well-known and conventional techniques. *See generally* Ex. 49, ¶¶63, 70-73. This includes obtaining a stool sample from a screened human donor, separating the fecal bacteria from rough particulate matter or separating fiber from the stool, and homogenizing the stool mixture. *See id.*, ¶75; *see also* Ex. 2 at 23:1-17.

It is undisputed that each of these activities involves well-known and conventional steps, Ex. 49, ¶¶61-63, 77-79, 84-86, and the use of such routine and conventional techniques does not transform a patent ineligible concept into a patentable one under *Alice* step two. *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1362 (Fed. Cir. 2017); *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377-78 (Fed. Cir. 2015) ("well-understood, routine, conventional activities" do not satisfy *Alice* step two).

Beyond these "separation" steps, the only other limitations add well-known, routine, and conventional elements: packaging (such as an enema kit or an oxygen-resistant container) and additives that have no claimed function (specifically a cryoprotectant, an antioxidant, and saline). None are necessary to render the fecal bacteria effective. Ex. 49, ¶¶63-69, 80-83, 87-89. Finch/UMN's expert, Dr. Mazmanian, lacking any substantive or evidence-backed response to this observation, retreated to *ipse dixit* postulations: that they are "expected to" make the FMT treatment better. *Compare* Ex. 48, ¶¶50, 58, 73 (making an empirical but unquantified and unsubstantiated assertion that it "*will* have an impact . . . on viability of the fecal bacteria" (emphasis in original)) *with generally* Ex. 49, ¶¶90-230 (claim-by-claim analysis of the

categories of limitations). But even if true, it does not matter whether such additives might make pharmaceutical compositions better; for the purposes of the Court's § 101 analysis, what matters is whether the "invention," as claimed, is sufficiently broad to encompass ineligible subject matter. *See Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1149 (Fed. Cir. 2016).

Dr. Mazmanian primarily focuses on the claims' inclusion of a cryoprotectant. He argues that the fecal flora combined with a cryoprotectant has "markedly different characteristics than naturally occurring fecal flora." Ex. 48, ¶42. In particular, he opines without any data that the presence of an antioxidant or cryoprotectant—but particularly the cryoprotectant—converts the composition into something more than the fecal bacteria alone. *Id.*, ¶¶49-51.

Dr. Mazmanian further argues that, during prosecution of a different (unasserted) claim from a different (unasserted) patent, Dr. Borody overcame a Section 101 rejection by the examiner, referring to the "pomelo juice example" in the PTO's guidance on Nature-Based Product Claims. *Id.*, ¶¶52-54, 57. However, a key difference between the as-issued asserted claims of the Borody patents and the examiner's reasoning, quoted at length at *id.*, ¶¶54, 65, is that none of the claims cover "an effective amount" of a cryoprotectant or an antioxidant. Both the claims in the pomelo juice example, Ex. 52 at FINCH_UMN_0029366-67, and the draft Borody claims that were subject to the examiner's rejection included "effective amount" wording, Ex. 53 at FINCH_UMN_0005656. But that limitation is missing from the asserted claims for both the cryoprotectant and antioxidant elements. *Compare, e.g.*, Ex. 3 at cls. 8, 14 *with* Ex. 53 at FINCH_UMN_0005656-57. The asserted claims fail to recite an "effective amount," and are silent as to the function of those additives in the claimed invention.

The only arguable function of a cryoprotectant or antioxidant in the claimed compositions is to ensure that the compositions retained sufficient fecal flora to be "effective for treating

recurrence of a *C. difficile* infection" or "to overcome a *Clostridium difficile* infection," depending on the asserted claim (again noting that the claims of the '080 patent do not contain this limitation). But it is undisputed that a fecal slurry can be frozen without a cryoprotectant or antioxidant without impacting clinical success, Ex. 49, ¶65; Ex. 50, ¶17-18, meaning that the cryoprotectant or antioxidant is not necessary. *See also* Ex. 51 at FER_RBX03012341. This is true even if the fecal slurry consists of only stool and water. *Id.* at FER_RBX03012342-43.

Dr. Louie correctly observes that the asserted Borody claims are drafted to cover the addition of even a de minimis amount of cryoprotectant, which would have no effect on the claim elements relating to viability during freeze-thaw cycles. Ex. 49, ¶¶99, 123; *compare with* Ex. 48, ¶78. When at least one embodiment of a claim is directed to patent ineligible subject matter, the claim is invalid under Section 101. *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1294-95 (Fed. Cir. 2017) (citing MPEP § 2106 (9th ed. Mar. 2014)); *see also ChromaDex,* 59 F.4th at 1284 ("So the only difference between at least one embodiment within the scope of the claims and natural milk is that the NR in the former is isolated.").

Moreover, in the '193 patent, the claims require the composition to be "non-frozen," but never require that it be frozen, meaning that the cryoprotectant, which need not be present in any particular amount, performs no function vis-à-vis freezing in those claims. Similarly, the asserted claims of the '702 and '309 patents do not require that the composition be frozen at all. Thus, only the asserted claims of the '080 patent actually require freezing, and those claims do not include any limitations related to the amount of viable fecal flora remaining post-freezing. Ex. 7 So none of the asserted claims even require the supposed viability following freezing that is central to Dr. Mazmanian's analysis (and as shown above, naturally occurring stool exhibits sufficient viability even without a cryoprotectant in any case).

Dr. Mazmanian similarly argues, without data, that a composition with an added antioxidant is materially different from one without. Ex. 48, ¶¶65-68, 79-80. However, as with the cryoprotectant, the claims recite no threshold amount, no "effective amount," and no role for the antioxidant. Additionally, stool compositions without antioxidants retain sufficient fecal flora to prevent the recurrence of *C. difficile* infection. Ex. 49, ¶¶80-81. Thus, for the same reasons as above, this limitation adds nothing and does not render the claims patentable.

These additional components fail to convert the claims into something that is "significantly more" than claims to the ineligible concept itself. *Alice*, 573 U.S. at 217-18. Relying on these additional components would be an improper effort to circumvent Section 101 "by attempting to limit the use of [the idea] to a particular technological environment." *Id.* at 222.

IV. FERRING'S *DAUBERT* MOTION

A. Mr. Malackowski's $[redacted] up-front "access fee" is impermissible because it is not tied to infringement and is not based on comparable licenses

A reasonable royalty must be tied to infringement. Section 284 authorizes only damages "adequate to compensate **for the infringement**, but in no event less than a reasonable royalty **for the use made** of the invention by the infringer." 35 U.S.C. § 284 (emphasis added). The "hypothetical negotiation" concept, and the *Georgia Pacific* factors, are a means to estimate the reasonable royalty damages authorized by the Patent Act for the infringing use. The hypothetical negotiation is a hypothetical construct and may differ from a real-world negotiation, including in assuming a willing licensor and licensee, infringement, and the patents' validity. And, because the point of the hypothetical negotiation is to estimate damages for the infringing use, what else the parties might have agreed to in a real-world negotiation, such as part of a commercial collaboration agreement, does not form a proper part of the analysis.

Here, Mr. Malackowski opines that Ferring would have agreed to pay a $[redacted] up-

front access fee. That $[redacted] access fee cannot be a reasonable royalty for the infringing use because Mr. Malackowski admits his access fee would be paid even if there were no infringing sale. Ex. 8 at 39:10-40:8; 42:10-43:2. His opinion is not consistent with Federal Circuit law because it is not based on the use made of the invention. *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed. Cir. 2014). That is sufficient basis to exclude it.

Mr. Malackowski's up-front access fee opinion should also be excluded because it finds no support in comparable licenses. Licenses are comparable for purposes of estimating damages only if they are "commensurate with what the defendant has appropriated. If not, a prevailing plaintiff would be free to inflate the reasonable royalty analysis with conveniently selected licenses without an economic or other link to the technology in question." *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 872 (Fed. Cir. 2010). The Court's gatekeeping role requires it to exclude expert opinion unsupported by a technological comparability analysis. *See LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 79-80 (Fed. Cir. 2012); s*ee also TV Interactive Data Corp. v. Sony Corp.*, 929 F. Supp. 2d 1006, 1010, 1016 (N.D. Cal. 2013) (describing the court's "gatekeeping role" as requiring "some degree of comparability between licenses used in the *Georgia-Pacific* analysis for the jury to weigh"). And the "technology in question" is the patent claims, not the accused product or allegedly similar products.

Mr. Malackowski relies primarily on two business deals in an attempt to prop up his access fee theory: 1) a heavily redacted agreement (pulled from an SEC filing) between Seres Therapeutics and Nestle, where Nestle made both upfront and milestone payments to Seres in exchange for the right to commercialize a Seres drug and receive 50% of the resulting profits, Ex. 8 at 86:15-24, 96:6-13; and 2) the merger agreement where Ferring bought Rebiotix, Ex. 54. Neither provides the support needed to make Mr. Malackowski's opinion reliable.

As part of the first deal, Seres granted Nestle a license under certain unspecified patents (the patent numbers were redacted in the agreement on which Mr. Malackowski relies) relevant to those commercialization activities. Ex. 55 at FINCH_UMN_0019918, -20059 (1.40, Ex. B); *see also id.* at FINCH_UMN_0019912, -918 (1.1; 1.38-1.39). He testified that profits in the agreement referred to "essentially net revenues less true-ups for allowable expenses," and that Nestle bought the right to receive 50% of that amount. Ex. 8 at 86:15-24, 96:6-13. Many details are missing concerning the Seres/Nestle deal. Mr. Malackowski does not know whether the Seres product embodies the patents in suit, and figured it was "likely to embody other patents within the Finch portfolio, if at all . . . ." *Id.* at 183:3-10. Nor did Mr. Malackowski assess the value of the patent rights granted in the Nestle license, nor could he because the patents were redacted. *Id.* at 168:19-169:13. These concessions are fatal to Mr. Malackowski's reliance on the Nestle license. *ResQNet*, 594 F.3d at 871 (vacating damages award where patentee's expert "did not even attempt to show that these agreements embody or use the claimed technology or otherwise show demand for the infringed technology.").

Mr. Malackowski also references the merger agreement where Ferring bought Rebiotix. Ex. 56 at 55-60. Through the merger, Ferring acquired the entirety of Rebiotix, including physical and intangible assets, as well as the rights to REBYOTA (which at the time was under development) and other products under development, including certain patent rights. Ex. 54. For this entire package, Ferring made a [redacted] up-front payment. Ex. 54 at FER_RBX-2738157-58. Mr. Malackowski admits that this merger agreement "is not a license agreement" but insists that its economic terms—an upfront payment, milestone payments, and an "earnout" based on sales—"resemble the economic terms of license agreements" and thus are somehow relevant. Ex. 56 at 59. Mr. Malackowski made no effort to value the intellectual property

conveyed to Ferring in the merger agreement, as compared to the value of the REBYOTA product itself, the other products under development, or any of the other development efforts or technology transferred as part of that agreement. Ex. 8 at 71:22-72:6 ("I don't believe it's necessary in the context of this hypothetical to conduct that apportionment."), *see also id.* at 123:6-20. Nor did he make any effort to compare the intellectual property transferred as part of the merger to the patents in suit. *Id.* at 73:8-15. Mr. Malackowski thus failed to establish how this agreement is relevant, much less comparable, to the license the parties would have arrived at in the hypothetical negotiation. Mr. Malackowski's up-front access fee opinion—and any other opinion based on the Nestle/Seres and Ferring/Rebiotix deals—therefore should be excluded.

B. Mr. Malackowski errs in asserting that the hypothetical license would include an exclusive grant of rights

Mr. Malackowski's errors are not limited to his up-front access fee theory. He also insists that the hypothetical license would have been exclusive on the theory that the parties would have wanted to negotiate for exclusivity. Ex. 56 at 68. That is legal error. The parties might have theoretically negotiated a sale of the company in a real-world negotiation, but that doesn't mean that a reasonable royalty includes the purchase price for it. The reasonable royalty is for the use that was made of the patented technology. *Aqua Shield*, 774 F.3d at 770. Mr. Malackowski conceded, as he must, that (assuming Finch has standing, *see* D.I. 208) Finch in fact retained the right to practice and license to third parties patents it owns and that it will retain that right after trial, so the use of the patented technology is by definition non-exclusive. Ex. 8 at 24:10-25:7. Ferring cannot be made to pay for a benefit that it would not get, and Mr. Malackowski's insistence to the contrary is legal error. *Trell v. Marlee Elecs. Corp.*, 912 F.2d 1443, 1447 (Fed.

Cir. 1990).[1] Mr. Malackowski's opinion that the license would be exclusive should be excluded.

C. Mr. Malackowski's [redacted] royalty rate fails to apportion value

Finally, Mr. Malackowski fails to conduct any analysis of "the incremental value that the patented invention adds to the end product" when arriving at his [redacted] royalty rate (or his up-front access fee, for that matter). *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014). As this Court recognized in *Bio-Rad Laby's, Inc. v. 10X Genomics, Inc.*, "[t]he Federal Circuit has repeatedly emphasized the importance of apportionment as part of a district court's gatekeeping function." No. 15-cv-152-RGA, 2018 WL 4691047, at *8 (D. Del. Sept. 28, 2018); *see also Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 30 F.4th 1109, 1123 (Fed. Cir. 2022); *Finjan LLC v. SonicWall, Inc.,* 84 F.4th 963, 976 (Fed. Cir. 2023). In *Roche*, the Federal Circuit held that when an expert relies on a comparable license for apportionment the expert must show that the asserted comparable license is "sufficiently comparable in that principles of apportionment were effectively baked into the purportedly comparable license." 30 F.4th at 1123. Apportionment is required even when the accused product is not comprised of multiple components, *First Quality Tissue, LLC v. Irving Cons. Prod. Ltd.*, No. 19-cv-428-RGA, 2022 WL 958089, at *12 (D. Del. Mar. 30, 2022), or where claims cover all of a product, *Exmark Mfg. Co. v. Briggs & Stratton Power Prod. Grp., LLC*, 879 F.3d 1332, 1349 (Fed. Cir. 2018).

V. CONCLUSION

For the foregoing reasons, Ferring requests that the Court grant its motions.

---

[1] Georgia-Pacific Factor 3 requires considering if the license is exclusive or non-exclusive. *Georgia-Pac. Corp. v. U.S. Plywood Corp*., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified sub nom. Georgia-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc*., 446 F.2d 295 (2d Cir. 1971). That should not be read to suggest, though, that the premise of the hypothetical negotiation can be an exclusive license, but rather that the nature of the license must be considered relative to other licenses that might be used as a benchmark.

Of Counsel:

Joshua P. Davis
WOMBLE BOND DICKINSON (US) LLP
811 Main Street
Suite 3130
Houston, TX 77002
Telephone: (346) 998-7801
Joshua.P.Davis@wbd-us.com

Christian E. Mammen
WOMBLE BOND DICKINSON (US) LLP
50 California Street, Suite 2750
San Francisco, CA 94111
Telephone: (415) 765-6267
Chris.Mammen@wbd-us.com
Ben.Bourke@wbd-us.com

Daralyn J. Durie
Matthew Chivvis
Rachel Dolphin
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
Telephone: 415-268-6055
ddurie@mofo.com
mchivvis@mofo.com
rdolphin@mofo.com

Sara Doudar
MORRISON & FOERSTER LLP
701 Wilshire Boulevard
Los Angeles, CA 90017
Telephone: 213-892-4345
sdoudar@mofo.com

Evelyn Li-Jin Chang
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, CA 94304
Telephone: 650-813-4033
evelynchang@mofo.com

Dated: December 8, 2023

WOMBLE BOND DICKINSON (US) LLP

/s/ Mary W. Bourke
Mary W. Bourke (#2356)
Dana K. Severance (#4869)
Daniel M. Attaway (#5130)
Zachary Murphy (#6881)
1313 North Market Street, Suite 1200
Wilmington, DE 19801
Telephone: (302) 252-4320
Mary.Bourke@wbd-us.com
Dana.Severance@wbd-us.com
Daniel.Attaway@wbd-us.com
Zachary.Murphy@wbd-us.com

John B. Bourke (#6534)
WOMBLE BOND DICKINSON (US) LLP
50 California Street, Suite 2750
San Francisco, CA 94111
Telephone: (415) 765-6267
Ben.Bourke@wbd-us.com

Attorneys for Ferring Pharmaceuticals Inc. and Rebiotix Inc.

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that a true and correct copy of the foregoing was served on December 8, 2023 upon the following attorneys of record via electronic mail:

Kelly E. Farnan
Nicole K. Pedi
Jeffrey L. Moyer
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
Telephone: (302) 651-7700
farnan@rlf.com
pedi@rlf.com
moyer@rlf.com

KIRKLAND & ELLIS LLP

Michael W. De Vries
Ingrid Petersen
555 South Flower Street, Suite 3700
Los Angeles, CA 90071
(213) 680-8400
michael.devries@kirkland.com
ingrid.petersen@kirkland.com

Adam R. Alper
555 California Street, 27th Floor
San Francisco, CA 94104
(415) 439-1400
adam.alper@kirkland.com

Patricia A. Carson
Ashley Ross
Leslie Schmidt
Nancy Kaye Horstman
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
patricia.carson@kirkland.com
ashley.ross@kirkland.com
leslie.schmidt@kirkland.com
kaye.horstman@kirkland.com

Alina Afinogenova
200 Clarendon Street, 47th Floor
Boston, MA 02116
(617) 385-7500
alina.afinogenova@kirkland.com

Ashley Cade
1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 389-3381
ashley.cade@kirkland.com

Dated: December 8, 2023

/s/ Mary W. Bourke
Mary W. Bourke (#2356)
WOMBLE BOND DICKINSON (US) LLP
1313 North Market Street, Suite 1200
Wilmington, DE 19801
Telephone: (302) 252-4320
Mary.Bourke@wbd-us.com

Attorneys for Ferring Pharmaceuticals Inc. and Rebiotix Inc.